PBT Management & Listing: Purpose Statement & Discussion

First of all – Some broader terms often used in PBT discussions

Virtual Elimination – an overall strategy that requires different approaches – some preventative, some remedial – to control or eliminate different inputs and *in situ* contamination. Applies to all sources - point and non-point - from all media. Applies to new and existing chemicals. (Once persistent toxic substances have been released into the ecosystem, it is not practical to completely remove them, especially from open waters, bottom sediments, or contaminated groundwater. Therefore the qualifier "virtual" is appropriate as applied to eliminated the presence of persistent toxics substances from the ecosystem.)
IJC – A Strategy for the Virtual Elimination of Persistent toxic Substances, August, 1993.

Continually Reduce – The Ecology PBT Strategy envisions continually reducing risks to human health and Washington's environment from exposures to PBTs, using the following goals:

- Reduce and phase-out existing sources of PBT chemicals.
- Clean up PBT chemicals from historical sources.
- Prevent new sources of PBT chemicals.
- Build partnerships to promote efforts to reduce and eliminate PBT chemicals.
- Improve regulatory and non-regulatory approaches.
- Identify and prioritize additional PBT chemicals.
- Improve public awareness and understanding of PBT problems and solutions.
- Promote the development of information needed to make informed decisions on measures to reduce PBT chemicals.

Ecology – Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State, December , 2000.

Management – The (Canadian Toxic Substances Management Policy) has two key management objectives:

- virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative (Track 1 substances); and

- **management** of other toxic substances and substances of concern, throughout their entire life cycles, to prevent or minimize their release into the environment (Track 2 substances).

Environment Canada – Toxic Substance Management Policy, 1995

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

What is the purpose of the PBT List?

The primary purpose behind Ecology's efforts to develop PBT List is to identify chemicals that the Department believes requires greater attention because of their persistence, bioaccumulation potential and toxicity characteristics. A decision to include a chemical on a PBT List will not trigger a specific set of reduction goals or schedules. It is expected that the reduction goals and requirements for chemicals appearing on a PBT List will vary from chemical to chemical. Ecology intends to use a PBT List in the following four ways:

- *Chemical Action Plans:* Ecology will use a PBT List to identify chemicals for which the Department will prepare chemical-specific action plans. Chemical-specific action plans are a central feature of the PBT Strategy and provide a mechanism for identifying and evaluating additional measures to reduce and, where possible, eliminate current sources and uses of individual PBT chemicals.

- *Monitoring:* Ecology will use a PBT list to identify PBTs that are a priority for additional environmental monitoring.

- *Voluntary Measures:* In addition, based on the recommendations for action developed in each individual CAP, Ecology will use a PBT List to identify PBT chemicals that are priorities for voluntary reductions. This is consistent with the primary purpose behind EPA's efforts to identify PBT chemicals as part of the National Waste Minimization Plan.[1]

- *Information Collection and Dissemination:* The PBT List will also provide a mechanism for increasing public awareness on the problems associated with PBT chemicals and steps that individuals, communities, governments, and business/agriculture might take to reduce PBT chemicals and uses. This is particularly important given that further reductions in sources and uses could necessitate changes in consumer behavior and alternative product availability.

[1] Under the Government Performance and Results Act, EPA has committed to reduce PBT chemicals in hazardous waste by 50% by the year 2005 (relative to a 1991 baseline). In 1998, EPA published a draft RCRA PBT List that was designed to help guide voluntary waste minimization efforts. That rule has not been finalized. However, EPA is currently working on a revised list that is scheduled to be published as agency guidance in spring 2002.

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

Approach to Establishing Criteria

Background: Definitions of P, B, and T

Persistence, Bioaccumulation & Toxicity definitions in the Ecology PBT Strategy

Chemicals and/or pollutants that

P: remain in the environment for a long time (persist) without breaking down;

B: accumulate in the environment and build up in the tissues of humans, fish, and animals; and

T: are toxic (causing cancer and other health problems) to living organisms, including humans

Other definitions of P, B and T

Persistence

- The tendency of a substance to remain in the environment without transformation or breakdown
- A measure of how long a chemical is expected to exist in the environment and thus be available for exposure
- Chemical compounds that, to a varying degree, resist photochemical, biological and chemical degradation.
- Environmental persistence refers to the length of time a substance resides in environmental media and is usually defined in terms of half-life -- the time required for the concentration of a substance to diminish to half its original value. A persistent substance degrades very slowly in the environment and therefore has a long half-life. Physical, chemical and biological processes that degrade a substance are considered in determining its half-life; dilution or transportation to other locations or media generally are not.

Bioaccumulation

- Chemicals that can increase from relatively low environmental concentrations found in the air, water, soil, or sediment to harmful levels in plants or animals.
- Measured as a BAF/BCF ratio or as a BCF or BAF
- Bioaccumulation describes the process by which a substance accumulates in a living organism -- either from the surrounding medium or through food containing the substance. A substance's potential to bioaccumulate can be expressed by the bioaccumulation factor (BAF), the bioconcentration factor (BCF) or the octanol-water partition coefficient (Kow). The BAF and the BCF measure the concentration of a substance in a living organism relative to its concentration in the surrounding medium.
- The BAF accounts for substance intake from both food and the surrounding medium, while the BCF accounts for intake from the surrounding medium only. The octanol-water partition coefficient (Kow) estimates a substance's tendency to partition from water to organic media, such as lipids present in living organisms. The partition coefficient can be used in place of the BCF or BAF when limited experimental data are available.

Toxicity

- WMPT assigns toxicity scores based on three health and ecological endpoints
  - Human carcinogen
  - Non-cancerous effects – ability to cause acute and chronic adverse effects on human receptors
  - Ecological effects – ability to cause acute and chronic adverse effects on environmental receptors

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

Thresholds to use to define a chemical as a PBT

Table 2 from Ecology PBT Working List: Responses to Public Comments on Appendix E, June 2002

Table 2

Summary of Criteria Used by Other Organizations to Identify PBT Chemicals

Agreement/Organization	Persistence	Bioaccumulation	Toxicity	Listed pollutants
Criteria used to identify candidates for bans, phaseouts, or reductions (OME, 1993)	Half Life > 2 days air; 6 months water or soil; or 1 year sediment.	BAF/BCF > 5000 or LogKow > 5	Acute and chronic (including toxicity of breakdown products)	27 pollutants
Environment Canada (1994) – Accelerated Reduction/ Elimination of Toxics (ARET)	Environmental half life > 50 days.	BCF > 500 (Substances with BCF between 250 and 500 flagged for data collection)	Evaluation to produce normalized toxicity score (NTS). NTS > 40 (Max=60)	16 substances or groups of substances.
EPA – Water Quality Criteria (1995)	Half life in water, sediment or biota > 56 days	BAF > 1000	Potential to cause adverse effects.	16 substances or groups of substances.
Great Lakes Bi-National Toxics Strategy (GLNPO, 1997)	Half life > 56 days (high), 7- 56 days (moderate) and < 7 days (low)	BAF > 5000 (high); 1000 – 5000 (moderate); and < 1000 (low)	Substances that appear on one or more existing toxic substance lists.	12 Level I substances and 14 Level II substances.
North American Commission on Environmental Cooperation (1997)	Half Life > 2 days air; 6 months water or soil; or 1 year sediment.	BAF/BCF > 5000 or LogKow > 5	Acute and chronic (including toxicity of breakdown products)	
EPA – National PBT Strategy (EPA, 1998a)	Half life > 56 days (high0, 7-56 days (moderate) and < 7 days (low)	BAF > 5000 (high); 1000 – 5000 (moderate); and < 1000 (low)	Substances that appear on one or more existing toxic substance lists.	12 Level I substances identified by the Great Lakes National Program Office
EPA – Waste Minimization Program (1998b)	Regional half life > 580 hrs (high); 140 – 580 hrs (medium); and < 140 days (low)	BAF/BCF > 1000 (high); 250 – 1000 (medium); and < 250 (low)	Potential to cause cancer, non-cancer and ecological effects.	53 pollutants
EPA – Toxics Release Inventory (EPA, 1999a)	Half life in water, sediment, soil > 2 months; air > 5 days	BAF/BCF > 1000	Chemicals on Great Lakes Level I List or receiving high WMPT scores.	19 substances
EPA – Office of Pollution Prevention and Toxics (EPA, 1999b)	Half life in water, sediment, soil > 2 months; air > 5 days	BAF/BCF > 1000	New or existing chemicals undergoing review under the Toxics Substances Control Act.	
United Nations Environmental Programs/Persistent Organic Pollutants (UNEP, 2001)	Half life > (2 or 6) months in water; 6 months in soil/sediment or other evidence that substance is sufficiently persistent to be of concern.	BAF/BCF > 5000 or LogKow > 4 or 5; evidence that substance with lower BCF/BAF is of concern or monitoring indicates concern.	Chronic toxicity or ecotoxicity data indicate a potential for damage human health or the environment due to long-range transport.	11 chemicals and chemical groups
Ecology PBT Working List	**Regional half life > 580 hrs**	**BAF/BCF > 1000**	**Potential to cause cancer, non-cancer and ecological effects**	**22 chemicals or chemical groups**

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

Table of Various PBT Criteria

	Persistence	Bio-accumulation	Long-range transport potential	Toxicity (2)	Protection goals and risk management
UN-ECE POPs Protocol	Half-life in water > 2 months **or** in sediment > 6 months **or** in soils > 6 months	BCF **or** BAF > 5000 or log K_{ow} > 5	Vapour pressure < 1000 Pa **and** half-life in air > 2 days **or** monitoring data in remote area	Potential to adversely affect human health and/or environment	Control, reduce or eliminate discharges, emissions and losses of POPs
Stockholm Convention	Half-life in water > 2 months **or** in sediment > 6 months **or** in soils > 6 months	BCF or BAF > 5000 **or** log K_{ow} > 5 **or** monitoring data in biota	Measured levels far from source **or** monitoring data in remote area **or** multi-media modeling evidence **and** half-life in air > 2 days	Evidence of adverse effect on human health or the environment **or** toxicity characteristics indicating potential damage to human health or environment	Objective is to protect human health and the environment from POPs. Reduce or eliminate releases
CEC Sound Management of Chemicals	Half lives: 2 days (air); or 6 months (water); or 1 year (sediments) or 6 months (soil)	Preferably field-generated BAF^3 5000, $BCF\ ^3$5000 or $\log K_{ow}{}^3$ 5	Monitoring evidence of transboundary environment transport for POPs (e.g., appearance in biota) or indirect evidence of transport potential (e.g., air persistence ^{3}2 days, and volatility £1000 Pa for POPs	Potential to adversely affect human health and/or environment	Control, reduce or eliminate discharges, emissions and losses of POPs
EU PBT criteria	Half-life > 60 days in marine water **or** > 40 days in freshwater (1) **or** > 180 days in marine sediment	BCF > 2000	Not applicable	Chronic NOEC < 0.01 mg/l or CMR cat 1&2 or endocrine disrupting effects	No risk assessment based on PEC/PNEC ratio. Sources inventory and emission reduction measures without risk assessment

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

	Persistence	Bio-accumulation	Long-range transport potential	Toxicity (2)	Protection goals and risk management
	or > 120 days in freshwater sediment (1)				
EU vPvB criteria	Half-life > 60 days in marine or freshwater **or** > 180 days in marine or freshwater sediment	BCF > 5000	Not applicable	Not applicable	Phase out or ban (may be authorization of production as intermediate in close systems)
US EPA New Chemicals Policy	Transformation half-life > 2 months	BCF > 1000	Not applicable	Toxicity data based on level of risk concern	Testing and release control required
US EPA Presumption of a Ban	Transformation half-life > 6 months	BCF ≥ 5000	Not applicable	Toxicity data based on level of risk concern	Commercialization denied except if testing justifies removing chemical from "high risk concern."
Canada Toxic Substances Management Programme (TSMP)	Half-life in Air >2 days Water >6 months Sediment >1 year Soil >6 months	BAF or BCF > 5000 or log K_{ow} > 5	Not applicable	Toxicity according to Canadian EPA	Risk assessment: If toxic and P and B and primarily anthropogenic, then virtual elimination
Canadian Domestic Substances List (DSL)	Half-life in Air >2 days Water >6 months Sediment >1 year Soil >6 months	BAF or BCF > 5000 or log K_{ow} > 5	Not applicable	Inherently toxic (3)	If inherently toxic and P or B : screening level risk assessment but even if P & B no virtual elimination unless determined by risk assessment

(1) For marine environment risk assessments, half-life data in freshwater and freshwater sediment can be overruled by data obtained under marine conditions.
(2) (2) L(E) $C_{50;}$ NOEC – no observed effect concentration; CMR – carcinogenic, mutagenic or toxic to reproduction.
(3) The definition of "inherently" toxic to non-human organisms is still under consideration by Environment Canada

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

Thresholds currently used elsewhere and in strategy document

Persistence

- **Water:** > 60 days (2 months) to > 6 months (180 days)
- **Sediment:** > 180 days (6 months) 120 days in freshwater sediment, 180 days in marine sediment
- **Soil:** > 6 months
- **Air:** > 2 days

Bioaccumulation

- BCF > 1000 to BCF > or equal to 5000
- BAF or BCF > 5000

Or

- LogKow > 5

Toxicity

- Potential to adversely affect human health and/or environment.
- Evidence of adverse effect on human health or the environment or toxicity characteristics indicating potential damage to human health or environment
- Toxicity data based on level of risk concern
- Chronic NOEC < 0.01 mg/l or CMR category 1 & 2 or endocrine disrupting effects

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

Tradeoffs associated with different threshold levels

Key Questions Ecology has addressed to determine P, B, and T:

Criteria for identifying PBT chemicals

- What characteristics should be considered when evaluating chemicals for inclusion on the PBT List?
    - Persistence, Bioaccumulation and Toxicity (Cancer, Non-Cancer & Ecological);
    - Persistence and Toxicity; and/or
    - Bioaccumulation and Toxicity

Parameters, sources of information, characterization measures, appropriate threshold criterion

- What parameters should Ecology use to characterize persistence, bioaccumulation, & toxicity (cancer, non-cancer & ecological)?
- What are sources of sound scientific information is there for persistence, bioaccumulation, & toxicity (cancer, non-cancer & ecological)?
- Given the variability in study results and environmental conditions, what measure should Ecology use to characterize persistence, bioaccumulation & toxicity (cancer, non-cancer & ecological)?
- What is an appropriate threshold criterion for persistence, bioaccumulation & toxicity (cancer, non-cancer & ecological)?

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

"Presence in Washington" as a criteria for listing

As the draft Ecology PBT Working List was being developed, Ecology used a combination of qualitative and quantitative information to determine whether there is a reasonable basis to conclude that a chemical has been:

- used in Washington,
- released by Washington sources, or
- found in Washington's environment.

The following data sources were used:

- Washington State Fish Consumption Advisory List,
- the ATSDR Hazdat database for Washington State,
- the 303(d) List,
- the Ecology SEDQUAL information system,
- Ecology's Environmental Information Management (EIM) database,
- the Toxics Release Inventory,
- MTCA Site List and
- the National Toxics Inventory.

This information was supplemented by information from the Puget Sound Ambient Monitoring Program, the Department of Agriculture and other sources.

Reasons why Ecology included the "presence in WA criteria" (as the draft PBT Working List was being developed):

- To identify chemicals that may require additional measures to reduce uses, releases, or concentrations in Washington. Consequently, the need to consider available information on uses, sources, and environmental presence is explicitly reflected in the purpose behind creating the PBT Working List. The consideration of such factors is consistent with the preparation of other hazardous substance list (e.g., Sediment Management Standards, Hazardous Air Pollutants, MTCA Method A Cleanup Standards).
- Qualitative information on uses, sources and environmental presence should be considered in making a determination on whether there is a sufficient basis to include a chemical on the draft PBT Working List.

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

- There are limited practical benefits associated with including chemicals on the draft PBT Working List that are not an issue in Washington.
- The PBT Strategy should focus on PBTs that pose potential environmental threats in Washington.

Should Ecology include a substance on the PBT list when there is no information on the use, release or environmental presence in Washington?

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

Basis for setting criteria: link to those used by other entities or develop WA specific

Link PBT criteria and list to those used by other entities

In the PBT Strategy, Ecology first used utilized EPA's PBT list of 12 chemicals (less those not present in Washington's environment). As the draft PBT Working List was developed, Ecology reviewed several existing PBT criteria and accompanying lists, and selected the criteria used in EPA's Waste Minimization Prioritization Tool (WMPT). Primary rationale for that selection included:

Consistency

Criteria in use and being applied elsewhere

WMPT criteria has gone through the science and policy test and public review

Developing a WA specific criteria

When developing the draft PBT Working List, Ecology considered trying to develop a "Washington specific criteria", given that some lists may not be applicable to Washington state specific issues and environmental problems. Limited resources to develop a criteria specific for Washington state precluded further efforts at that time.

Other issues – identified by Advisory Committee members

Metals

US EPA

EPA has recently released a second draft of "Framework for Metals Risk Assessment". Hazard and risk assessments of metals and metal compounds raise issues not generally encountered with organic chemicals. In recognition of the unique assessment issues raised by metals and the complexity of addressing these issues consistently across the Agency's various programs, the Agency's Science Policy Council tasked an Agency work group to develop metals assessment guidance. The guidance is intended to assure:

1) a consistent application of scientific principles for assessing hazard and risk for metals,
2) state-of-the-science application of methods and data,
3) a transparent process (i.e. articulating assumptions and uncertainties), and
4) the flexibility to address program-specific issues.

This guidance will be provided in two documents; a Framework for Metals Assessment, and a Guidance for Characterizing and Ranking Metals.

This report is a science-based document that focuses on the special attributes and behaviors of metals and metal compounds affecting human health and ecological risk assessments. The Framework document will not be a prescriptive guide on how any particular type of assessment should be conducted within a US EPA program office. Rather, it is intended to make recommendations and foster the consistent application of methods and data to metals risk assessment in consideration of the unique properties of metals.

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

United Nations Economic Commission for Europe

The Executive Body adopted the Protocol on Heavy Metals on 24 June 1998 in Aarhus (Denmark). It targets three particularly harmful metals:

- cadmium,
- lead and
- mercury.

According to one of the basic obligations, Parties will have to reduce their emissions for these three metals below their levels in 1990 (or an alternative year between 1985 and 1995). The Protocol aims to cut emissions from industrial sources (iron and steel industry, non-ferrous metal industry), combustion processes (power generation, road transport) and waste incineration. It lays down stringent limit values for emissions from stationary sources and suggests best available techniques (BAT) for these sources, such as special filters or scrubbers for combustion sources or mercury-free processes. The Protocol requires Parties to phase out leaded petrol. It also introduces measures to lower heavy metal emissions from other products, such as mercury in batteries, and proposes the introduction of management measures for other mercury-containing products, such as electrical components (thermostats, switches), measuring devices (thermometers, manometers, barometers), fluorescent lamps, dental amalgam, pesticides and paint.

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

Approach to listing PBTs – Facilitated Discussion

Chemicals listed in the strategy document

Options for the type of list

- **One list**
- **Tiered List**

How to deal with uncertainty and "gray areas" in listing chemicals

COMMENT/FEEDBACK/DISCUSSION from Advisory Committee

Managing the criteria and lists over time -- Facilitated Discussion

How to provide for flexibility in response to changing science

How to provide for certainty of what chemicals are listed as PBTs

Process for revisions to criteria & listed chemicals